

REMARKS

Claims 1-16, 18-77, and 113-140 are pending. Claims 27-35, 48-77, and 113-140 are withdrawn as directed to nonelected subject matter. Claims 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47 read on the elected species; claims 1-5, 7, 9, 11, 36-41 and 45 are withdrawn as directed to unelected species.

35 U.S.C. § 112 Rejections

Reconsideration is respectfully requested of the rejection of claims 1-4, 9-13, 15-20, 24, 26 and 30-37 under 35 U.S.C. § 112, 1st and 2nd paragraphs. However, applicants believe that this rejection was intended by the Office to apply to claims 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47. Applicants note that the specification discloses the manner and process of making biocathodes and biofuel cells as claimed, and that the Office has not shown that there is reason to doubt the objective truth of the statements made in the specification. In this case, Applicant provides ample guidance in selection of each of the components of the claimed bioanode (e.g., electron conductors, electron mediators, electrocatalysts, enzymes, and enzyme immobilization materials) and discloses several examples of working bioanodes. Therefore, the specification must be taken as in compliance with the enablement requirement. Applicants cite *in re Marzocchi* wherein

[as] a matter of Patent Office practice, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

. . .

It is incumbent on the Patent Office whenever a rejection [for enablement] is made, to explain *why* it doubts the truth or accuracy of any statement in the supporting disclosure and to back up such assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.¹

¹ M.P.E.P. § 2164.04; *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971).

Moreover, in *U.S. v. Telectronics, Inc.*, the Federal Circuit held that the claims were enabled

where the "claims literally comprehend numerous polymers in addition to the one specifically described in appellant's specification" because no persuasive reason was given by the Patent Office why the specification does not realistically enable one skilled in the art to practice the invention as broadly as it is claimed.²

The patent at issue was directed to a system for healing bone fractures by delivering a current to the fracture site. The exemplified system had a stainless steel cathode operating at 5-20 μ A, but the claims were not limited to a specific metal/current combination. Similarly, the instant claims do not limit the enzyme immobilization material to the exemplified embodiment, the specification provides ample guidance regarding other materials that could be used as an enzyme immobilization material,³ and the Office has not provided a persuasive reason why the specification does not realistically enable one skilled in the art to practice the invention.

Further, the bioanode components can function as follows. The electrons flow from the enzyme to the electrode, the bioanode comprises an electron conductor, a reduced form of an electron mediator capable of donating electrons to the electron conductor to produce an oxidized form of the electron mediator, an enzyme capable of reacting with the oxidized form of the electron mediator and an enzyme immobilization material comprising the electron mediator. When an electrocatalyst is used, a reduced form of the electrocatalyst donates electrons to the electron conductor to produce an oxidized form of the electrocatalyst and this oxidized form of the electrocatalyst reacts with a reduced form of an electron mediator. Claim 6 requires these reactions to occur and transport of the electron mediators and electrocatalysts through the immobilization material (e.g., membrane) allow these reactions to occur. Thus, claim 6 and the claims that depend therefrom satisfy 35 U.S.C. § 112, 1st paragraph and 35 U.S.C. § 112, 2nd paragraph.

² *U.S. v. Telectronics, Inc.*, 8 U.S.P.Q.2d 1217, 1224 (Fed. Cir. 1988), quoting *In re Bowen*, 492 F.2d 859, 863, 181 U.S.P.Q. 48, 51-52 (C.C.P.A. 1974).

³ See specification at paragraphs [0038]-[0040].

Obviousness-type Double Patenting Rejection

Reconsideration is respectfully requested of the rejection of claims 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47 as unpatentable over claims 1-27, 29-35, and 42-44 of copending U.S. Patent Application No. 10/931,147. Contrary to the Office's position, the enzymes used in the bioanode to oxidize a fuel fluid and enzymes used at the biocathode to reduce an oxidant are different and have different reduction potentials. The instant claims describe an electrocatalyst layer that is adjacent to the electron conductor wherein the term "adjacent" is defined in the specification as "physically or chemically connected by appropriate means."⁴ Thus, the immobilization material described in the instant claims does not conduct electrons. However, claims 1-27, 29-35, and 42-44 require an electron-conducting enzyme immobilization material. Thus, the claims 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47 are patentable over claims 1-27, 29-35, and 42-44 of copending Application No. 10/931,147.

35 U.S.C. § 103 Rejections

Reconsideration is requested of the rejection of claims 6, 8, 10, 12, 42-44 and 47 as unpatentable over Karyakin, claims 17-22 as being unpatentable over Karyakin in view of Jin, claims 6, 13-16 and 23-26 as being unpatentable over Zawodzinski in view of Gregg, and unspecified claims as being unpatentable over Zawodzinski in view of Gregg and Khan under 35 U.S.C. § 103. Applicants note that the outstanding rejections do not give any patentable weight to the enzyme stabilization criteria in the pending claims (e.g., the stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days while continuously reacting with the electron mediator). While the element "at least about" in claim 6 would allow for retention of activity of somewhat less than 30 days, the magnitude of the difference in lifetime is the important aspect. For example, claim 6 distinguishes the art of record because the cited references would have described or suggested an enzyme stability of only 13 hours upon continuous use as noted in Applicants' last response. An enzyme stability of 13 hours would not be interpreted to meet the "at least about 30 days" requirement. Thus, claims 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47 are patentable over the cited

⁴ See specification at paragraph [0056].

references for this reason and for the further reasons as described in detail in the previous response under 35 U.S.C. § 103.

Rejoinder

Pursuant to M.P.E.P. §821.04, Applicants again request rejoinder of withdrawn claims 27-35, 49-52, 60-62, 114, and 117-130 as they depend from claim 6 and therefore require all the limitations of claim 6. Applicants further request reconsideration of withdrawn unelected species claims 1-5, 7, 9, 11, 36-41, and 45 because they either require all the limitations of claim 6 or overlap the scope of claim 6.

CONCLUSION

Applicant submits that the present application is in condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,

A handwritten signature in black ink, reading "Janet S. Hendrickson". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Janet S. Hendrickson, Ph.D., Reg. No. 55,258
SENNIGER POWERS LLP
100 North Broadway, 17th Floor
St. Louis, Missouri 63102
(314) 231-5400

JSH/clp